EXHIBIT C

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, WA

Appeal of:	**VEIN AND WELLNESS GROUP LLC**	OMHA Appeal No.:	**3-5702338364**
Beneficiary:	**[Multiple]**	Medicare Part:	B
Medicare No.:	**[Multiple]**	Before:	**Andrea Barraclough** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, a **PARTIALLY FAVORABLE** decision issues for the physician's surgical services (billed under code 37241) that Appellant provided to the following beneficiaries on the following dates of service: beneficiary W.M. on dates of service June 10, 2014 (claim # 9716292900473), June 12, 2014 (claim # 9716292900474), June 17, 2014 (claim # 9716292900475), and July 8, 2014 (claim # 9716292900476); beneficiary G.H. on dates of service June 16, 2014 (claim # 9716292900478) and June 30, 2014 (claim # 9716292900479); beneficiary W.C. on dates of service August 7, 2014 (claim # 9716292900500) and August 19, 2014 (claim # 9716292900501); beneficiary M.S. on dates of service July 23, 2014 (claim # 9716293471000), July 30, 2014 (claim # 9716293900045), and August 6, 2014 (claim # 9716293900052); beneficiary A.W. on dates of service September 22, 2015 (claim # 9716293900385) and November 12, 2015 (claim # 9716293900387); beneficiary G.T. on date of service May 8, 2014 (claim # 9716293900390); beneficiary L.F. on date of service June 2, 2014 (claim # 9716293900395); beneficiary R.B. on dates of service October 1, 2015 (claim # 9716293900399), October 13, 2015 (claim # 9716293900401), and October 15, 2015 (claim # 9716293900402); beneficiary J.Y. on date of service November 17, 2015 (claim # 9716293900406); beneficiary J.N. on date of service September 9, 2015 (claim # 9716293900419); beneficiary J.K. on dates of service July 8, 2014 (claim # 9716293900420), July 15, 2014 (claim # 9716293900421), and July 2, 2015 (claim # 9716293900422); and beneficiary S.F. on dates of service June 9, 2014 (claim # 9716293900443) and June 11, 2014 (claim # 9716293900444).

Medicare shall cover and pay for all of the claims at issue except one; specifically, claim # 9716293900401 as to beneficiary R.B. for date of service October 13, 2015, is not covered or payable.

PROCEDURAL HISTORY

A. Case Events

Appellant sought reimbursement for surgical services under CPT code 37241. The claims were originally paid, however the Recovery Audit Contractor (RAC) overturned coverage and issued several overpayment demands on October 26 and November 4, 2016. File 6, pgs. 549-553, 538-542, 555-559.

The Medicare Administrative Contractor (MAC) denied the claims at issue in redetermination decisions dated June 20, 2016 (as to W.M), *see* File 6, pgs. 398-401, 419-422, 461-464, 377-380); December 20, 2016 (as to M.S., R.B., J.K., and S.F.), *see* File 6, pgs. 313-316, 334-337, 292-295, 208-211, 29-33, 60-63, 229-232, 39-42, 187-190, 250-253, 10-14); and December 21, 2016 (as to G.H., W.C., A.W., G.T., L.F., J.Y., and J.N.), *see* File 6, pgs. 440-443, 355-358, 482-485, 503-506, 165-168, 81-84, 271-274, 144-147, 102-105, 123-126.

On March 3, 2017, the Qualified Independent Contactor (QIC) consolidated all of the instant claims into a single case number and denied all of the claims on reconsideration. File 4, pgs. 1-12. The QIC decision is an appealable initial determination per 42 C.F.R. § 405.920 and § 405.926.

On March 16, 2017, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely request for a hearing by an Administrative Law Judge (ALJ) that met all jurisdictional requirements, which continued to consolidate the claims into a single case number. File 1, pgs. 2-7. In its request for hearing, Appellant did not indicate that it had new evidence to present and none was presented at the time of hearing. *Id.* Thus, no good cause to admit new evidence analysis is required.[1]

Pursuant to proper notice, Appellant's hearing was conducted on June 24, 2021. Attorney Debra Parrish appeared as counsel for Appellant. No other parties appeared for the hearing. *Id.* At the hearing, Exhibits (Files) 1-14 were admitted without objection. After the hearing, Exhibits (Files) 15 and 16 (Notices of Hearing), 17 (Amended Notice of Hearing), 18 (Hearing Audio Recording), and 20 and 21 (additional medical records) were administratively admitted.[2] Thus, this ALJ enters and considers Exhibits (Files) 1 through 21 (excluding duplicates and Exhibit 19) in rendering this decision.

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1 The medical records at Files 20 and 21 are not newly offered evidence requiring a good cause analysis. Appellant has many similar claims across many case numbers currently in the OMHA appeal process, and she has essentially submitted all records for all of her patients with active appeals. Appellant had two mutli-beneficiary claims before this ALJ with hearings weeks apart. All of these records were submitted and intended to be placed in all pertinent case files; however, these particular records were only uploaded into this ALJ's earlier case. Subsequent to this instant hearing when Ms. Parrish notified the ALJ that the relevant medical records were sent along with the earlier case packet, this ALJ requested the records to be uploaded into this particular case as well.

2 A record related to another of Appellant's cases was inadvertently added as Exhibit 19 in the instant case. Once that error was detected, Exhibit 19 was removed from this record, resulting in there being no Exhibit 19 in this case.

ISSUES

1. Were the physician's surgical services properly billed under CPT code 37214 such that they are covered and payable for the dates of service?

2. If the services are not covered, do the limitation of liability provisions under Section 1879 of the Act or any other law apply? If not, who is financially responsible?

APPLICABLE LAW AND POLICY

I. Scope and Standard of Review

A. Scope of Review

The issues before the ALJ include all issues established in the initial, redetermined, or reconsidered claims and appeals that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). The ALJ may decide a case on the record and not conduct a hearing if the Appellant and all other parties indicate in writing that they do not wish to appear before the ALJ. 42 C.F.R. § 405.1038. Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision will be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

B. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the entirety of the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate all of the evidence without regard to the findings or prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

The burden of proving each element of a Medicare claim lies with the Appellant, who must prove their case by a preponderance of the evidence. *See* Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030.

II. Applicable Law (Medicare Sections/ Regulations/Other Authority)

A. Authority

All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII and XIX of the Act, and all implementing Codes of Federal Regulations (CFRs) are binding on ALJs. 42 C.F.R. § 405.1063. National Coverage Determination (NCD) guidelines are also binding precedent for ALJs and are the only source of

regulation that establishes or changes substantive legal standards governing the scope of Medicare benefits or payments. 42 C.F.R. § 405.1060.

The Centers for Medicare and Medicaid Services (CMS) and its contractors can and do issue non-binding policy guidance describing criteria for coverage of selected types of medical items and services in the form of manuals (CMS Manuals), local medical review policies (LMRPs), and Local Coverage Determinations (LCDs). ALJs will give substantial deference to LCDs, LMRPs, or CMS Manuals when applicable, and if they do not follow these policies, they must explain why in their decision. *See* 42 C.F.R. § 405.1062.

Prior decisions of the Medicare Appeals Council (the Council), which is the Level 4 appeals level for Medicare claims governed by the Departmental Appeals Board, are not binding unless the Chair of the Departmental Appeals Board deems them precedential. 42 C.F.R. § 405.1063. In all other cases, a decision of the Council may act as persuasive guidance from which the ALJ may depart at their discretion.

B. Medicare Generally

Sections 1831 and 1832 of the Act, and 42 C.F.R. § 410, establish the Supplemental Medical Insurance Program for the aged and disabled under Part B and outline Part B benefits and entitlements. Under § 1832(a)(2)(B) of the Act, Medicare will make direct payment to a medical or other health services provider or contractor that has provided medical services or equipment to a beneficiary. However, Medicare will not make payment unless sufficient information exists determining that the amount is proper and should be paid. 42 U.S.C. § 1395l, 42 C.F.R. § 424.5(6).

It is the responsibility of an Appellant to furnish sufficient information and documentation to support its claims for a Medicare payment. 42 C.F.R. § 424.5(a)(6). No adjudicator is under an obligation to seek additional documentation or supplement the record.

Section 1870 of the Act provides the authority for waiver of overpayments and other payment adjustments for incorrect payments on behalf of individuals. Overpayments shall not be recovered with respect to an individual who is "without fault." 42 U.S.C. § 1395gg.

C. Law Related to Condition and Service at Issue

1. Binding Authority - *Part B and Outpatient Services*

The Supplementary Medical Insurance program (Part B of Title XVIII of the Social Security Act) provides coverage for (1) a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, (2) for outpatient hospital services, and (3) for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. The term "physicians' services" is defined in Section 1861(q) of the Act as professional services performed

by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)[an intern or a resident-in-training]).

The non-binding LCDs are discussed below.

FINDINGS OF FACT AND ANALYSIS

After careful consideration of the entire record, a preponderance of the evidence establishes the following:

A. Factual Findings

Hearing Statements

1. At the hearing, Ms. Parrish argued that this case regards a Mechanical Occlusion Chemically Assisted Ablation (MOCA) treatment and whether CPT code 37241 was the appropriate code for the doctor to bill on the date of service. File 10:43-15:06, 15:41-20:55. The MOCA procedure did not yet have its own CPT code in 2014 and 2015. *Id.* Dr. Kelly O'Donnell (provider for Appellant company and client of Ms. Parrish) had been using 37241 in the absence of a specifically applicable code. *Id.* The actual on-point codes for MOCA (which are 36472 and 36473) did not come out until 2017. *Id.* The application process for getting a specific code generated for the MOCA procedure began in 2016 and took about a year to complete. *Id.*

2. In 2016, Novitas started visiting users of the MOCA procedure to tell them not to use code 37241 anymore, and to use the general surgery code 37999 in the interim until the MOCA-specific codes were approved. *Id.* Once Novitas told her to use the general surgery code, Dr. O'Donnell did—however, this all happened in 2016, after the dates of service here. *Id.*

3. Ms. Parrish argued that the MAC's and QIC's rationale for denial was incorrect. *Id.* More specifically, the MAC applied L34924/ L32678 to the claims at issue; however, those codes are only for sclerotherapy and not the MOCA procedure. *Id.* Further, the MAC's denial rationale, that sclerotherapy should not be performed on great saphenous veins, is inapposite to the case at bar, as sclerotherapy was not performed on the great saphenous veins in these cases—the MOCA procedure was performed. *Id.* Still further, the QIC's rationale was wrong also, as even though they acknowledged these were MOCA procedures being performed, they reasoned that sclerotherapy was the correct procedure to analyze and LCD L34924/ L32678 was the correct LCD apply because Dr. O'Donnell used a sclerotherapy agent in the surgery. *Id.* However, the QIC failed to account for the fact that it is standard practice for the same agent (sodium tetradecyl sulphate or STS) to be used in both sclerotherapy and MOCA procedures; the liquid form is used in sclerotherapy while the foam form is used in the MOCA procedure. *Id.* Thus, just because the same agent is used does not mean the procedures are the same.

4. Ms. Parrish described the differences between the MOCA procedure and sclerotherapy. *Id.* In MOCA, a catheter is placed in the vein and the catheter turns around inside

the vein to open it up; it is a non-thermal embolization method used in areas where there is a risk of nerve injury. *Id.* Part of this process is that foam STS agent is placed inside the vein to form a temporary plug, and the catheter causes a vibration off the plug that helps open to vein. *Id.* In sclerotherapy, medication is injected into the vein, and it flushes out any blockages; it is primarily used for cosmetic purposes. *Id.* Also, sclerotherapy is used on small veins while MOCA is used on larger veins. *Id.* In liquid form as used in sclerotherapy, STS agents dissolve; in foam form as used in MOCA, the STS agent solidifies and must be retrieved out of the vein after the procedure so as not to block the vein or cause air bubbles. *Id.*

5. Ms. Parrish also noted that, back in 2016 when the contractors made the site visit to Dr. O'Donnell, they did not inform her to follow LCD L34924 and L32678 requirements to get coverage nor tell her to use sclerotherapy CPT codes; instead they told her to use the miscellaneous surgery code. *Id.* This infers that the contractor is aware of MOCA's differences to sclerotherapy. *Id.*

Documentation for Beneficiary W.M.

6. Related to claim # 9716292900473, the record shows the beneficiary underwent a MOCA procedure on June 10, 2014, relevant to diagnosis code 454.0, Leg Varicosity with Ulcer. File 21, pg. 400. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 10 cm of the beneficiary's right small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

7. Related to claim # 9716292900474, the record shows the beneficiary underwent a MOCA procedure on June 12, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 401. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 60 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

8. Related to claim # 9716292900475, the record shows the beneficiary underwent a MOCA procedure on June 17, 2014; the record does not contain a diagnosis code. File 21, pg. 402. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 55 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

9. Related to claim # 9716292900476, the record shows the beneficiary underwent a MOCA procedure on July 8, 2014; the record does not contain a diagnosis code. File 21, pgs. 404-406. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

10. As to all claims numbers for W.M., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 21, pgs. 396-397.

Documentation for Beneficiary G. H.

11. Related to claim # 9716292900478, the record shows the beneficiary underwent a MOCA procedure on June 16, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pgs. 191-192. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 40 cm of the beneficiary's left great saphenous vein. *Id*. This record describes the procedure in detail. *Id.*

12. Related to claim # 9716292900479, the record shows the beneficiary underwent a MOCA procedure on June 30, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pgs. 193-195. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 42 cm of the beneficiary's right great saphenous vein. *Id*. This record describes the procedure in detail. *Id.*

13. As to all claims numbers for G.H., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 21, pgs. 187-188.

Documentation for Beneficiary W.C.

14. Related to claim # 9716292900500, the record shows the beneficiary underwent a MOCA procedure on August 7, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 13. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 57 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

15. Related to claim # 9716292900501, the record shows the beneficiary underwent a MOCA procedure on August 19, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 12. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 42 cm of the beneficiary's left great saphenous vein. *Id*. This record describes the procedure in detail. *Id.*

16. As to all claims numbers for W.C., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 21, pgs. 8-10.

Documentation for Beneficiary M.S.

17. Related to claim # 9716293471000, the record shows the beneficiary underwent a MOCA procedure on July 23, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pg. 200. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 35 cm of the beneficiary's right great saphenous vein. *Id*. This record describes the procedure in detail. *Id.*

18. Related to claim # 9716293900045, the record shows the beneficiary underwent a MOCA procedure on July 30, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pg. 201. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 25 cm of the beneficiary's right small saphenous vein. *Id*. This record describes the procedure in detail. *Id.*

19. Related to claim # 9716293900052, the record shows the beneficiary underwent a MOCA procedure on August 6, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pgs. 202-203. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 60 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

20. As to all claims numbers for M.S., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 197-198.

Documentation for Beneficiary A.W.

21. Related to claim # 9716293900385, the record shows the beneficiary underwent a MOCA procedure on September 22, 2015, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pgs. 325-326. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's right small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

22. Related to claim # 9716293900387, the record shows the beneficiary underwent a MOCA procedure on November 12, 2015, relevant to diagnosis code I87.2 Venous Insufficiency, R60.0 Localized Edema, M79.662 Pain Lower Left Leg. File 20, pgs. 328-329. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 28 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

23. As to all claims numbers for A.W., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 319-320.

Documentation for Beneficiary G.T.

24. Related to claim # 9716293900390, the record shows the beneficiary underwent a MOCA procedure on May 8, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pgs. 230-231. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 40 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

25. As to the claim number for G.T., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 226-227.

Documentation for Beneficiary L.F.

26. Related to claim # 9716293900395, the record shows the beneficiary underwent a MOCA procedure on June 2, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21,

pgs. 89-90. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

27. As to the claim number for L.F., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 21, pgs. 76-77.

Documentation for Beneficiary R.B.

28. Related to claim # 9716293900399, the record shows the beneficiary underwent a MOCA procedure on October 1, 2015, relevant to diagnosis codes I87.2, R60,0, I83.012, L97.212, M79.661. File 14, pgs. 832-833. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 20 cm of the beneficiary's right small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

29. Related to claim # 9716293900402, the record shows the beneficiary underwent a MOCA procedure on October 15, 2015, relevant to diagnosis codes I87.2, R60.0, M79.605. File 14, pgs. 835. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

30. As to all claim numbers for R.B., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 14, pgs. 828-829.

31. There is a surgical record for R.B. for a date of service of October 6, 2015, *see* File 2, pgs. 387-390; however, this is not a contested date of service. There is no surgical record in the file for date of service October 13, 2015. Thus, as to claim # 9716293900401, there is no documentary evidence to support the occurrence of the procedure on the date billed.

Documentation for Beneficiary J.Y.

32. Related to claim # 9716293900406, the record shows the beneficiary underwent a MOCA procedure on November 17, 2015, relevant to diagnoses codes I87.2, I87.312, L97.222, and M79.662. File 20, pgs. 355-357. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

33. As to all claims numbers for J.Y., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 351-352.

Documentation for Beneficiary J.N.

34. Related to claim # 9716293900419, the record shows the beneficiary underwent a MOCA procedure on September 9, 2015, relevant to diagnosis code 454.8 Varicose Veins Leg. File 20, pgs. 41-42. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's left small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

35. As to the claim number for J.N., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 226-227.

Documentation for Beneficiary J.K.

36. Related to claim # 9716293900420, the record shows the beneficiary underwent a MOCA procedure on July 8, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 275. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 60 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

37. Related to claim # 9716293900421, the record shows the beneficiary underwent a MOCA procedure on July 15, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 276. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 65 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

38. Related to claim # 9716293900422, the record shows the beneficiary underwent a MOCA procedure on July 2, 2015, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 277. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 38 cm of the beneficiary's left small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

39. As to all claims numbers for J.K., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 21, pgs. 271-272.

Documentation for Beneficiary S.F.

40. Related to claim # 9716293900443, the record shows the beneficiary underwent a MOCA procedure on June 9, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 100. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 40 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

41. Related to claim # 9716293900444, the record shows the beneficiary underwent a MOCA procedure on June 11, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 21, pg. 101. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

42. As to all claims numbers for S.F., the record contains a Letter of Medical Necessity drafted by Dr. O'Donnell, which establishes the beneficiary's need for the MOCA procedures at issue. File 20, pgs. 319-320.

B. Analysis

1. Issue # 1 - Were the physician's surgical services properly billed under CPT code 37214 such that they were covered and payable on the date of service?

For all twelve beneficiaries, the MAC denied the services at issue because the documentation did not meet the requirements of the sclerotherapy LCD. *See* File 6, pgs. 398-401, 419-422, 461-464, 377-380, 313-316, 334-337, 292-295, 208-211, 29-33, 60-63, 229-232, 39-42, 187-190, 250-253, 10-14, 440-443, 355-358, 482-485, 503-506, 165-168, 81-84, 271-274, 144-147, 102-105, and 123-126. The QIC denied the claims because it felt L34924/ L32678 was/were the correct LCD (depending on the date of service) to apply because Dr. O'Donnell used a sclerotherapy agent in the surgeries. File 4, pgs. 1-12.

Appellant's argument is that the provider did, in fact, perform MOCA procedures and not sclerotherapy, such that the MAC was factually incorrect in applying L34924/ L32678. *See* File 18. Further, Appellant asserts that the coding used for the procedure was accurate at the time of the date of service and that the use of a sclerotherapy agent in the MOCA procedure is irrelevant to its coverage. *Id.*

First, this ALJ finds that Dr. O'Donnell indeed performed MOCA procedures on each patient, as opposed to sclerotherapy. While the surgical record documents mention the words "sclerotherapy volume," this refers only to a sclerotherapy agent that is used in the MOCA procedure, and not the actual procedure used. Further, this ALJ finds Ms. Parrish's argument and explanation of the difference between the liquid STS agent used in sclerotherapy and the foam STS agent used in MOCA persuasive, in that even if they both use STS agents, this does not mean that the MOCA and sclerotherapy procedure are the same or that they should be governed by the same LCD.

Accordingly, neither LCD L34924 nor L32678 (depending on the date of service), as cited by the MAC and QIC, apply; this is because these LCDs do not address the MOCA procedure. Thus, inconsistent with the conclusions of the MAC and QIC, there was no LCD on the dates of service that either governed or limited coverage in these cases.[3] As there was no LCD on point on the dates of service for any of these twelve beneficiaries, MOCA will be covered where it is generally medically reasonable and necessary.

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3 LCD L32678 was retired on September 30, 2015, and replaced by LCD L34924, which was effective October 1, 2015, through December 31, 2016. Notably, L24924 was also related to sclerotherapy and not the MOCA specifically, rendering it too inapposite. The first instance of MOCA being added to any LCD did not occur until January 1, 2018, when it was added to LCD L33575.

This leaves the issue of whether CPT code 37241 was an appropriate code under which to bill. Based on the testimony and argument presented at the hearing, this ALJ finds credible that, in 2014, the MOCA procedure was a relatively new FDA-approved procedure for which an LCD had not yet been created and for which a CPT code had not yet been established. This ALJ finds credible that in the absence of an applicable CPT code, Dr. O'Donnell was using guidance from the manufacturer and a commercial insurer that code 37241 was the closest appropriate CPT code under which to bill the MOCA. Because there was no applicable policy that precluded the use of this code and the standard practice at the time for at least 50% of like surgeons and at least one commercial payer was to use this code, a preponderance of the evidence supports that the service at issue herein was validly coded. This is especially true where CMS did not tell Dr. O'Donnell to use CPT code 37999 until 2016, after the date of service in this case. Thus, this ALJ finds the CPT coding at the time to be proper.

That said, under § 1832(a)(2)(B) of the Act, coverage can only apply where there is evidence in the record supporting that an item or service billed was actually provided. In all claims in this case, save one, the record contains the MOCA surgical report for each procedure billed. *See* Statement of Facts Nos. 6-42. Thus, there is evidence supporting both the provision of the procedure and that the services were correctly coded in a majority of the claims herein.

However, there is one surgical record missing, which is the surgical record for R.B. for date of service October 13, 2015, related to claim # 9716293900401. Though this ALJ does not doubt that the procedure occurred and does not suspect a fraudulent billing, the lack of a surgical record fails to meet the preponderance of evidence burden, such that technicalities of § 1832(a)(2)(B) of the Act are not met. Thus, as to this one and only claim, the decision is unfavorable.

Accordingly, this decision is partially favorable to Appellant.

2. Issue # 2- If the services were not covered, do the limitation of liability provisions under Section 1879 of the Act apply? If not, who is financially responsible?

As noted, coverage is available for all but one of the services billed, and those covered claims should be paid by Medicare.

Because coverage for the single MOCA procedure (claim # 9716293900401) was denied based on a lack of documentation of medical reasonableness and necessity, this ALJ considers whether the limitation of liability provision of § 1879 of the Act is applicable. This requires considering whether the beneficiary and/or the provider knew or could reasonably have been expected to know that the services would be excluded from Medicare coverage. 42 U.S.C. § 1395pp.

§ 1879 of the Social Security Act, 42 U.S.C. § 1395pp, applies when a beneficiary or provider did not know, and could not reasonably have been expected to know, that Medicare would not cover the services. A provider of services is deemed to have actual or constructive

knowledge of non-coverage based upon its receipt of CMS notices (e.g. manual or written guides produced by the Government, or directives issued by Medicare contractors), or its knowledge of what are considered acceptable standards of practice by the local medical community. CMS (formerly HCFA) Ruling 95-1; *see also* 42 C.F.R. § 411.406. In determining the beneficiary's knowledge of non-coverage, the regulations presume that the beneficiary lacks the requisite knowledge unless a written notice of non-coverage has been provided to the beneficiary. 42 C.F.R. § 411.404.

The record contains no Advanced Beneficiary Notice (ABN) notifying the beneficiary that Medicare will likely not pay for the MOCA procedure. Thus, the beneficiary could not have reasonably been expected to know he would be liable for uncovered therapy sessions provided during the month of October of 2014. Accordingly, the beneficiary is relieved from liability. 42 U.S.C. § 1395pp(f).

The provider's financial liability, however, is not limited for the non-covered services, as it is presumed to have actual or constructive knowledge of rules governing Medicare documentation requirements where it receives CMS notices and has knowledge of acceptable standards of practice by the local medical community. CMS Ruling 95-1; 42 C.F.R. § 411.406(e). Here, the burden is on Appellant to ensure and verify that all services adequately documented. Accordingly, Appellant bears the financial burden of the non-covered costs for the non-covered services.

Section 1870(b) of the Social Security Act, 42 U.S.C. § 1395gg(b), prohibits recovery of Medicare overpayments under certain conditions. Appellant here is a provider of health care services and a participant in the Medicare program. It had access to the pertinent statutes, regulations, coverage determinations, coding rules, and Medicare manuals that set out the requirements for reimbursement under the Medicare program. Its failure properly to apply the guidance means that it is not without fault; therefore, Appellant does not meet the statutory requirement to avoid recoupment of the overpayment. Accordingly, Medicare may recoup any overpayment arising from uncovered portions of this claim.

CONCLUSIONS OF LAW

1. As to services provided to: beneficiary W.M. on dates of service June 10, 2014 (claim # 9716292900473), June 12, 2014 (claim # 9716292900474), June 17, 2014 (claim # 9716292900475), and July 8, 2014 (claim # 9716292900476); beneficiary G.H. on dates of service June 16, 2014 (claim # 9716292900478) and June 30, 2014 (claim # 9716292900479); beneficiary W.C. on dates of service August 7, 2014 (claim # 9716292900500) and August 19, 2014 (claim # 9716292900501); M.S. on dates of service July 23, 2014 (claim # 9716293471000), July 30, 2014 (claim # 9716293900045), and August 6, 2014 (claim # 9716293900052); beneficiary A.W. on dates of service September 22, 2015 (claim # 9716293900385) and November 12, 2015 (claim # 9716293900387); beneficiary G.T. on date of service May 8, 2014 (claim # 9716293900390); beneficiary L.F. on date of service June 2, 2014 (claim # 9716293900395); beneficiary R.B. on dates of service October 1, 2015 (claim #

9716293900399) and October 15, 2015 (claim # 9716293900402); beneficiary J.Y. on date of service November 17, 2015 (claim # 9716293900406); beneficiary J.N. on date of service September 9, 2015 (claim # 9716293900419); J.K. on dates of service July 8, 2014 (claim # 9716293900420), July 15, 2014 (claim # 9716293900421), and July 2, 2015 (claim # 9716293900422); and beneficiary S.F. on dates of service June 9, 2014 (claim # 9716293900443) and June 11, 2014 (claim # 9716293900444), Medicare coverage applies as it was appropriate for the physician's services to be billed by Appellant under CPT code 37241.

2. As to services provided to beneficiary R.B. on date of service October 13, 2015 (claim # 9716293900401), Medicare coverage does not apply as the documentation does not demonstrate reasonableness and necessity of this one particular procedure.

3. Medicare shall pay Appellant for all the previously uncovered services outlined in Conclusion No. 1. Medicare need not pay Appellant for the uncovered services outlined in Conclusion No. 2; Appellant is financially liable for the uncovered costs outlined in Conclusion No. 2.

ORDER

For the reasons discussed above, this decision is **PARTIALLY FAVORABLE.** The Medicare contractor shall process the claim in accordance with this decision.

SO ORDERED

Andrea R. Barraclough

Andrea Barraclough
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, WA

Appeal of: **VEIN AND WELLNESS GROUP LLC**	OMHA Appeal No.: **3-5702338364**
Beneficiary: **Multiple**	Medicare Part: **B**
Medicare No.: **Multiple**	Before: **Andrea Barraclough** Administrative Law Judge

Index of the Administrative Record and Exhibit List

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Exhibit Records for beneficiary A. WOOD	File Name	Administrative File Reference Page Range
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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

Exhibit Records for beneficiary G. TAYLOR		Administrative File Reference Page Range
	File Name	
Medical & Related: Medical Records	File 19	1 : 426
Medical & Related: Medical Records	File 20	1 : 380
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Exhibit Records for beneficiary G. HALL	Administrative File Reference	Page Range
	File Name	
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Exhibit Records for beneficiary J. NICOWSKI	Administrative File Reference	Page Range
	File Name	
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Medical & Related: Medical Records	File 20	1 : 380
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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

Exhibit Records for beneficiary J. YINGLING	Administrative File Reference		
	File Name	Page Range	
Medical & Related: Medical Records	File 19	1	: 426
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Procedural - CMS Levels: Reconsideration	File 4	1	: 14
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Exhibit Records for beneficiary J. KING		Administrative File Reference Page Range
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Medical & Related: Medical Records	File 19	1 : 426
Medical & Related: Medical Records	File 20	1 : 380
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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

Exhibit Records for beneficiary L. FINNAN	Administrative File Reference	Page Range
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Medical & Related: Medical Records	File 20	1 : 380
Procedural - CMS Levels: Request Reconsideration	File 12	1 : 7
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Exhibit Records for beneficiary M. SPIVEY	Administrative File Reference	Page Range
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Medical & Related: Medical Records	File 19	1 : 426
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Exhibit Records for beneficiary R. BRYAN	Administrative File Reference	Page Range
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Exhibit Records for beneficiary S. FISCHER	Administrative File Reference: File Name	Page Range
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Exhibit Records for beneficiary W. MALSCH	Administrative File Reference	Page Range
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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

ATTACHMENT A

Beneficiary First Name	Beneficiary Last Name	Medicare No.
J.	Y[redacted]	*****4946A
A.	W[redacted]	*****5281A
G.	H[redacted]	*****3459A
W.	C[redacted]	*****7710A
M.	S[redacted]	*****4200A
J.	K[redacted]	*****7758A
L.	F[redacted]	*****8833A
W.	M[redacted]	*****4032A
G.	T[redacted]	*****4789A
R.	B[redacted]	*****9587A
J.	N[redacted]	*****2667A
S.	F[redacted]	*****2349A